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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,178	12/01/2003	Dennis O'Brien	S63.2-13172-US01	2053
490 7590 10/02/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 10/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

JP

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/725,178	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,7 and 15-24 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to applicant's amendment received 26 June 2007.

The examiner acknowledges the amendments made to the claims.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Barath** (U.S. Patent No. **5,616,149**).

Claim 1: Barath discloses an elongated balloon **2** defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration, and an elongated incising element **6** mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue, and a radially compressible sheath **17** mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision

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when said balloon is inflated into the second configuration (Figures 11-13; col. 5, lines 14-36).

Claim 2: Barath discloses a mounting pad **13** for attaching said incising element to said balloon (col. 5, lines 14-19).

Claim 8: Barath discloses said incising element **6** being a blade and said surface feature is a cutting edge (col. 5, lines 14-36).

Claim 10: Barath discloses said cutting edge of said blade **6** being embedded in said sheath **17** when said balloon **2** is initially in said first configuration, said cutting edge oriented relative to said balloon to cut through said sheath for exposure of said cutting edge to incise tissue during radial compression of said sheath (Figures 11-13; col. 5, lines 14-36).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**).

Claims 11-14: Barath discloses the claimed device except for the incising element being a round wire or made of a hardened polymer, and the sheath being made of a low durometer material or a porous polyurethane material. It would have been obvious to

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one of ordinary skill in the art at the time of invention to provide these materials to the incising element and sheath of Barath, since it was known in the art that these are beneficial as biocompatible materials that facilitate the cutting mechanisms in angioplasty procedures.

5. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**), as applied to Claim 2 above, and further in view of **Vigil** (U.S. Patent No. **5,320,634**).

Claim 3: Barath discloses the claimed device except for the incising element being partially encapsulated in said mounting pad and said mounting pad is bonded to said balloon.

Vigil teaches an incising element **31** being partially encapsulated in said mounting pad **32** and said mounting pad is bonded to said balloon **18** (Figure 3A; col. 4, lines 17-34). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the incising elements as partially encapsulated in said mounting pad, as taught by Vigil, to Barath in order keep the incising element covered or protected and more securely mounted to prevent detachment from balloon.

Claim 4: Barath discloses the sheath **17** being attached to said mounting pad **13** (Figures 12-13).

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6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**), as applied to Claim 1 above, and further in view of **Shiber** (U.S. Patent No. **6,730,105**).

Claim 5: Barath discloses the claimed device (see above discussion for Claims 1, 2, and 8 above), except for the sheath having a pair of sheath members positioned on said balloon to interpose said incising element between said sheath members.

Shiber teaches a sheath (upper surface of element **15**) having a pair of sheath members (on either side of cutting blade **54**) being positioned on said balloon to intersperse said incising element **54** between said sheath members (Figure 18; col. 6, lines 8-21). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pair of sheath members between the cutting blade, as taught by Shiber, to Barath in order to reduce the likelihood of the balloon or tissue being damaged by the cutting edge during introduction and advancement or withdrawal of the catheter in the vasculature.

7. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**) in view of **Shiber** (U.S. Patent No. **6,730,105**) and **Vigil** (U.S. Patent No. **5,320,634**).

Claims 9, 17, and 23: Barath does not expressly close the sheath member having an azimuthal width.

Shiber teaches a sheath member (upper surface of element **15**) having an azimuthal width  $w$ , and wherein said blade **54** has an azimuthal width,  $W$ , where said blade extends from said mounting pad, with  $w > 2W$  (Figure 18; col. 6, lines 8-21). It would have been obvious to one of ordinary skill in the art at the time of invention to provide said sheath members having greater than 2 times the azimuthal width of said blade, as taught by Shiber, to Barath in order to reduce the likelihood of the balloon or tissue being damaged by the cutting edge during introduction and advancement or withdrawal of the catheter in the vasculature.

Barath discloses the claimed device except for said blade being partially encapsulated in a mounting pad that is bonded to said balloon (see discussion for Claim 3 above).

Vigil teaches an incising element **31** being partially encapsulated in said mounting pad **32** and said mounting pad is bonded to said balloon **18** (Figure 3A; col. 4, lines 17-34). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the incising elements as partially encapsulated in said mounting pad, as taught by Vigil, to Barath and Shiber in order keep the incising element covered or protected and more securely mounted to prevent detachment from balloon.

***Allowable Subject Matter***

8. Claims 6, 7 and 15-24 are allowed. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a pair of sheath members mounted on an inflatable member and being on either side of an incising element, the sheath members formed as hollow tubes or being radially compressible in order to expose the incising element, as well as extending a radial distance from the balloon that is farther than the radial distance that the incising element extends from the balloon.

***Response to Arguments***

9. Applicant's arguments with respect to claims 6, 7 and 15-24 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments filed 26 June 2007 regarding claims 1-5 and 8-14 have been fully considered but they are not persuasive.

11. Applicant argues that the sheath in Barath does not radially compress to expose cutting edges. However, by nature of being between the tissue wall **7** and balloon **2**, the sheath is radially compressed while exposing the incising element and therefore Barath reads on this claim limitation.

12. Applicant argues that Shiber does not teach a pair of sheath members. However, the examiner asserts that the halves of **53** or **55** seen in Figure 18 read on a pair of sheath members on either side of the incising element being mounted on a balloon **77**.



***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M. J. Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER